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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,903	01/20/2006	David W. Morris	PP23369.0003/20366-034US1	3389

55255 7590 08/04/2009

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,903	MORRIS ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,38,40-45,48,52,54,55,58 and 79-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *32,38,40-45,48,52,54,55,58 and 79-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed August 17, 2007. Claims 1-78 were previously pending and were subject to an Election/Restriction requirement. In the response Applicants cancelled claims 1-31, 33-37, 39, 46, 47, 49-51, 53, 56, 57, 59-78 and added new claims 79-98. Claims 32, 38, 40-45, 48, 52, 54, 55, 58 and 79-98 are pending. The newly added claims require further Election/Restriction, since some of them belong to the previously presented groups, and some of them do not. Additional election of species is also required.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims claim(s) 32 and 38, drawn to a method of screening for anticancer activity of a drug candidate comprising: contacting a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 with an anticancer drug candidate; and monitoring an effect of the anticancer drug candidate on expression of the CA polynucleotide, wherein an anticancer drug candidate which reduces expression of the nucleic acid is identified as a drug having anticancer activity and wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity, classified in class 436, subclass 24, for example.

II. Claims 40, 41 and 79-94 (when detection of polypeptide is elected), drawn to a method for detecting cancer associated with expression of a polypeptide encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample, comprising: comparing a level of expression of the polypeptide in the

patient sample with a level of expression of the polypeptide in a normal sample, wherein an altered level of expression of the polypeptide in the patient sample relative to the level of polypeptide expression in the normal sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient sample, wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity, classified in class 435, subclass 7.1, for example.

III. Claim 42, drawn to a method for detecting cancer associated with expression of a polypeptide encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample, comprising: comparing a level of signaling activity of the polypeptide in the test sample with a level of signaling activity of the polypeptide in a normal sample, wherein an altered level of signaling activity of the polypeptide in the patient sample relative to the level of polypeptide signaling activity in the normal sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient sample, wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity, classified in class 435, subclass 7.8, for example.

IV. Claim 43, drawn to a method for detecting cancer associated with the presence of an antibody in a patient sample, wherein the antibody specifically binds a polypeptide having an amino acid sequence at least 95% identical to SEQ ID NO: 42, or immunogenic fragment thereof, the method comprising: comparing a level of said antibody in the patient sample with a level of said antibody in a control sample, wherein

an altered level of antibody in said patient sample relative to the level of antibody in the control sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient sample, wherein the polypeptide has signaling activity, classified in class 436, subclass 512, for example.

V. Claims 44, 45 and 48, drawn to a method for screening for a bioactive agent capable of modulating the activity of a CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 comprising:

a) contacting a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 or fragment thereof with a candidate bioactive agent; and

b) comparing the effect of the candidate bioactive agent on expression of the CA polynucleotide in the presence of the candidate agent to expression of the CA polynucleotide in the absence of the candidate agent; wherein a candidate bioactive agent which modulates the expression of the CA gene is identified as a bioactive agent capable of modulating the activity of a CAP and wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity, classified in class 435, subclass 7.1, for example.

VI. Claims 52 and 79-94 (with respect to detection of the level of mRNA), drawn to a method for diagnosing kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer comprising: comparing a level of nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample comprising human

prostate, lung, bladder, breast, stomach or colon tissue to a level of nucleic acid in a control sample, said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encoding a polypeptide with signaling activity; wherein an increase of at least 50% from the level of nucleic acid in the patient sample compared to the level of the nucleic acid in the control indicates that the patient has kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer, classified in class 435, subclass 91.2, for example.

VII. Claims 54, 55 and 58, drawn to a method for treating cancer comprising administering to a patient an inhibitor of a CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41, classified in class 514, subclass 1, for example.

VIII. Claims 95-98, drawn to a method of diagnosing kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer comprising:

a) determining the level of a nucleic acid that hybridizes under highly stringent conditions to a nucleic acid comprising a nucleotide sequence of SEQ ID NO:41 in a patient sample; wherein hybridization is performed at 50°C to 60°C in 5 X SSC (9 mM NaCl/0.9 mM sodium citrate); and

b) comparing said level of nucleic acid in (a) to a level of the nucleic acid in a second sample, said second sample comprising a negative control; wherein an increase of at least 50% between the level of the nucleic acid in (a) and the level of the nucleic acid in the second sample indicates that the patient has kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to methods with different goals, materials and method steps.

For example, the method of screening for anticancer activity of a drug candidate (Group I), the method of detecting cancer using a polypeptide (Group II), the method of detecting cancer by detecting a signaling activity of a polypeptide (Group III), the method of detecting cancer using an antibody (Group IV), a method of screening bioactive agent (Group V), a method of detecting cancer by detecting a level of nucleic acid expression (Group VI), a method of treating cancer (Group VII) and a method of detecting cancer by detecting a level of polynucleotide which hybridizes to a polynucleotide at least 95% identical to SEQ ID NO: 41 are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials differ significantly for each of the methods. For screening of anticancer drug activity using the polynucleotide, hybridization may be used. For cancer detection using polypeptide expression, fluorescencent cell counting may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-VIII are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VIII together.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species:

Group II

Species of cancer

A) kidney (claim 40, 79),

B) colon (claim 40, 79),

C) prostate (claim 40, 79),

D) breast (claim 40, 79),

E) stomach (claim 40, 79).

Group III

Species of cancer

A) kidney (claim 42),

B) colon (claim 42),

C) prostate (claim 42),

D) breast (claim 42),

E) stomach (claim 42).

Group IV

Species of cancer

A) kidney (claim 43),

B) colon (claim 43),

C) prostate (claim 43),

D) breast (claim 43),

E) stomach (claim 43).

Group V

Species of cancer

A) kidney (claim 45),

B) colon (claim 45),

C) prostate (claim 45),

D) breast (claim 45),

E) stomach (claim 45).

Group VI

Species of cancer

A) kidney (claim 52, 79),

B) colon (claim 52, 79),

C) prostate (claim 52, 79),

D) breast (claim 52, 79),

E) stomach (claim 52, 79).

Group VIII

Species of cancer

A) kidney (claim 95),

B) colon (claim 95),

C) prostate (claim 95),

D) breast (claim 95),

E) stomach (claim 95).

5. . The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37

CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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August 1, 2009